DEPARTMENT OF HEALTH AND HUMAN SERVICES

May 29, 1998

Sally L. Van Wert, Ph.D.
Manager, Regulatory Affairs - Biotechnology
AgrEvo USA Company
Little Falls Centre One
2711 Centerville Road
Wilmington, DE 19808

Dear Dr. Van Wert:

This letter is in regard to your genetically modified corn line containing transformation event CBH-351, about which you initiated consultation with the Agency in November of 1996. According to AgrEvo, the new corn variety has been rendered tolerant to glufosinate-ammonium herbicides through the expression of the *bar* gene derived from *Streptomyces hygroscopicus*. The new corn variety has also been modified to confer resistance to lepidopteran insects through expression of the *cry9C* gene from *Bacillus thuringiensis* subsp. *tolworthi*.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new corn variety on March 3, 1998. These communications informed FDA of the steps taken by AgrEvo to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that AgrEvo has concluded that corn grain and forage derived from the new variety are not materially different in composition, safety, or other relevant parameters from corn grain or forage currently on the market, and that they do not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF0041 and that will be maintained in the Office of Premarket Approval.

Based on the information AgrEvo has presented to FDA, we have no further questions concerning corn containing transformation event CBH-351 at this time. However, as you are aware, it is AgrEvo's continued responsibility to ensure that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/S/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition